

TCT-704

Long Term Results of COSTAS-I First-in-Human Study of the Colibri Heart Valve, A Pre-mounted, Pre-packaged, Low Profile Transcatheter Aortic Valve in a 14 French Delivery System

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Background: The 24 mm Colibri TAVI valve is pre-mounted and compressed upon its delivery balloon catheter at manufacture and is packaged ensheathed within a 14 French introducer, sterilized and ready for insertion into the patient, obviating typical valve rinsing, mounting and loading procedures. We report the results of the COSTAS-I study of the first-in-human cohort receiving the Colibri Transcatheter Aortic Valve (CTAV) in an initial feasibility study at up to 18 months of follow-up.

Methods: The primary endpoints were successful valve implantation, valve performance (gradient, area, jet velocity, regurgitation grade) and safety based on the incidence of Major Adverse Cardiovascular and cerebrovascular events (MACCE) at 30 days. An initial cohort of 5 patients was enrolled. All patients were NYHA class 3-4, with preserved ejection fraction. The average aortic valve mean gradient (MG) pre-procedure was 53 mmHg and the average aortic valve area (AVA) was 0.71 cm².

Results: The valve was implanted successfully by transfemoral approach in all cases. The mean MG decreased to 8.4 mmHg and mean AVA increased to 2.2 cm². There was no valvular regurgitation, no need for permanent pacemaker and no stroke. One case had mild paravalvular insufficiency. All patients were discharged home ambulatory. Latest follow-up at 18 months, 10 months and three more at 6 months showed no evidence of myocardial infarction, stroke, or kidney injury. There was no requirement for permanent pacemaker or repeat procedures. All patients are NYHA class 1. Most recent Echo-Doppler showed an average MG of 10 mmHg and AVA of 2.2 cm², no prosthetic valve insufficiency and only one patient with mild paravalvular leak.

Conclusions: In this first-in-human cohort, clinical outcome at up to 18 months after implantation showed sustained benefits. The COSTAS-I experience suggests that the Colibri low profile, ready-to-use TAVI technology is feasible and safe, can provide procedural efficiencies and enable the transfemoral treatment of patients with small femoral arteries. In a small cohort, a high AVA of 2.2 cm² preserved over time suggests that the valve design may minimize energy losses.

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Transcatheter Aortic Valve Implantation Outcomes With Self-Expandable and Balloon-Expandable Devices in Patients with Mixed Aortic Valve Stenosis

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Background: Prevalence of mixed aortic stenosis (MAS) in patients undergoing TAVI is unclear. Due to the particular pathophysiology of this condition, these patients could represent a high-risk group with regards to device malpositioning, post-procedural aortic regurgitation (PPAR) and other complications. To date no study has evaluated the performance of the commercially available Medtronic CoreValve (MCV) and Edwards Sapien / SAPIEN XT (ESV) valve in this particular subgroup of patients.

Methods: From November 2007 to September 2013 all patients with a documented baseline MAS condition that underwent transfemoral (TF) TAVI either with MCV or ESV, were included in this analysis. MAS patients were defined by the presence of at least moderate aortic stenosis (AS) associated with moderate or severe aortic regurgitation (AR). Outcomes were assessed according to valvular academic research consortium (VARC-2) criteria at 30 days, 1 and 2 years.

Results: Among 472 patients in whom a baseline echocardiographic data were available, 295 (62.4%) had a pure aortic stenosis (PAS) while 177 had MAS (37.6%). Of 177 MAS patients, 59 (33.3%) were treated with MCV and 83 (46.8%) with ESV through a TF approach. At 30 days there were no differences in all-cause mortality (5.2% vs. 2.4%; p = 0.391), cardiovascular mortality (3.4% vs. 2.4%; p = 0.724), device success (58.6% vs. 67.5%; p = 0.282) or early safety endpoint (34.5% vs. 25.3%; p = 0.237). However, a greater incidence of valve embolization (7.5% vs. 0%; p = 0.013), need for a second valve (9.4% vs. 0%; p = 0.005), permanent pacemaker implantation (28.8% vs. 9.8%; p = 0.010) and moderate to severe peri-prosthetic AR (PPAR; 12.1% vs. 0%; p = 0.001) was found in the MCV group. At 1 year there were no differences in all-cause and cardiovascular mortality (15.5% vs. 12.2%; p = 0.572, and 12.1% vs. 4.9%; p = 0.119). Finally, at 2 years, a greater all-cause (29.3% vs. 14.6%; p = 0.035) and cardiovascular mortality (21.1% vs. 4.9%; p = 0.001) was found in the MCV group.

Conclusions: MCV was associated with a greater incidence of moderate-to-severe PPAR and other intra- and peri-procedural complications in MAS patients that underwent TAVI.

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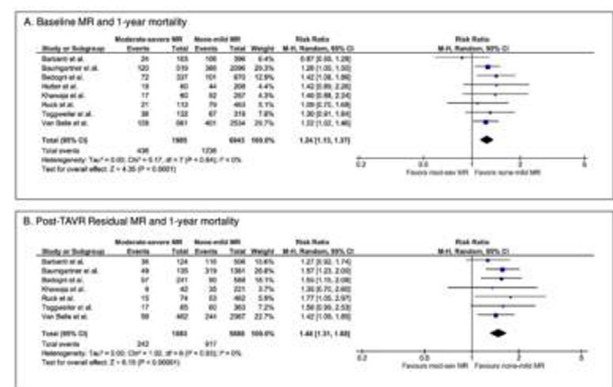
A Collaborative Meta-analysis of the Impact of Mitral Regurgitation on Outcomes after Transcatheter Aortic Valve Replacement: 8 Studies Involving 8919 patients

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Background: Significant mitral regurgitation (MR) is present in 20-30% of patients undergoing transcatheter aortic valve replacement (TAVR) and constitutes a significant co-existing valvular heart disease burden. We perform a meta-analysis and systematic review of literature to evaluate the impact of significant MR on outcomes after TAVR.

Methods: Eight studies comprising 8919 patients reporting TAVR outcomes based on the presence or absence of moderate-severe MR were included. Risk ratios (RR) were calculated using the inverse variance random effects model.

Results: None-mild MR was present in 77.8% and moderate-severe MR in 22.2% of the patients. The presence of baseline moderate-severe MR, compared to none-mild MR, was associated with increased mortality at 30-days (RR 1.24, 95% CI 1.13-1.37, p < 0.0001) and 1 year (RR 1.21, 95% CI 1.10-1.34, p = 0.0001; Figure 1A). The increased mortality associated with moderate-severe MR was not influenced by the etiology of MR (functional or degenerative MR) (RR 0.90, 95% CI 0.62-1.30, p = 0.56). The severity of MR improved in 61% ± 6.0% of patients after TAVR. Moderate-severe residual MR, compared to none-mild residual MR post-TAVR, was associated with significantly increased 1-year mortality (RR 1.48, 95% CI 1.31-1.68, p < 0.0001; Figure 1B).



Conclusions: Baseline moderate-severe MR results in increased mortality after TAVR. The severity of moderate-severe MR improves in the majority of patients undergoing TAVR. Significant residual MR post-TAVR is strongly associated with mortality; this may represent an important group to target with transcatheter therapies in future.

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Impact of Area Cover Index on the Incidence of Conduction Abnormalities after Implantation of Balloon-Expandable Aortic Prosthesis

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Background: While a certain degree of oversizing is required to reduce the incidence of paravalvular leakage, prosthesis oversizing (PO) might be associated with increased risk of conduction abnormalities leading to new pacemaker implantation. The aim of this study was to assess the impact of valve oversizing on conduction abnormalities